AMENDED IN ASSEMBLY MAY 9, 2011

AMENDED IN ASSEMBLY APRIL 4, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 378

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 139.3 and 5307.1 of the Labor Code, relating to workers' compensation.

LEGISLATIVE COUNSEL'S DIGEST

AB 378, as amended, Solorio. Workers' compensation: pharmacy products.

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of employment.

Existing law provides that it is unlawful for a physician to refer a person for specified medical goods or services, whether for treatment or medical-legal purposes, if the physician or his or her immediate family has a financial interest with the person or in the entity that receives the referral. A violation of this provision is a misdemeanor.

This bill would add pharmacy goods, as defined, to the list of medical goods or services for which it is unlawful for a physician to refer a person under this provision, except in prescribed circumstances. By creating a new crime, this bill would impose a state-mandated local program.

Existing law requires the administrative director, after public hearings, to adopt and revise periodically an official medical fee schedule that

establishes reasonable maximum fees paid for medical services, other than physician services, and for other prescribed goods and services, in accordance with specified requirements. Under existing law, prior to the adoption by the administrative director of a medical fee schedule for any treatment, facility use, product, or service not covered by a Medicare payment system, the maximum reasonable fee paid cannot exceed the fee specified in the official medical fee schedule in effect on December 31, 2003.

This bill would, for pharmacy services, drugs, or other pharmacy products not covered by a Medi-Cal payment system, instead make the maximum fee 83% of the average wholesale price, as defined, of the lowest priced product of equivalent therapeutic effect. This bill would, until the date that the administrative director adopts an official medical fee schedule for compounded drug products, as defined, set the maximum reasonable fee for compounded drug products and the ingredients as prescribed. This bill would not allow a fee for a compounded drug ingredient, as specified.

This bill would, until the date the administrative director adopts an official medical fee schedule specifically applicable to physician-dispensed products, require that the fee for any product, as defined, dispensed, as defined, by a physician not exceed the lesser of 120% of the physician's documented paid cost, as defined, or the physician's documented paid cost plus $250.

This bill would also delete obsolete provisions relating to the adoption of a medical fee schedule for patient facility fees for burn cases.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) In 2002, the Legislature passed Assembly Bill 749 (Chapter 6 of the Statutes of 2002), which directed an official medical fee schedule for pharmaceuticals to be created to contain workers'

compensation costs and to ensure that injured workers had access to appropriate treatment.

(b) Since the creation of the official medical fee schedule governing pharmaceuticals, there has been a growing practice by some prescribing physicians to utilize medications that are not covered by the fee schedule, to dispense these medications directly to workers' compensation patients, and to bill employers and insurers at highly inflated rates. These practices unfairly enrich the physicians who engage in these efforts, cost employers and insurers millions of dollars, and prevent these wasted dollars from being used to enhance benefits for injured workers.

(c) One of the ways that these physicians accomplished the goal of billing at inflated rates was by repackaging common medications from bulk supplies so that the packages did not have fee schedule codes, and dispensing them in common amounts at prices far above the fee schedule for the same products sold through pharmacies. This practice continued until the Administrative Director of the Division of Workers' Compensation adopted a regulation in 2007 that required any repackaged medication to be reimbursed at the same fee schedule as the same drug distributed through pharmacies and not reimbursed based on arbitrary prices associated with unscheduled packages.

(d) Prior to the adoption of the physician dispensing regulation, compounded medications, creams, copacks, and other medical foods constituted a small percentage of the overall cost of prescription medications. However, once the abusive repackaging practice was outlawed, the practice of physicians prescribing or dispensing compounded medications, creams, copacks, and medical foods expanded rapidly.

(e) The percentage of California workers' compensation medication dollars that are used toward compounded drugs, copacks, and medical foods has increased from 2.3 percent in 2006 to 12 percent in 2009. This increase in compounded drugs, copacks, and medical foods has increased costs for insurers and led to rising premiums for employers. For example, the State Compensation Insurance Fund reports that what was rarely billed prior to 2007 rapidly escalated to over $58 million in billings in a 16-month period. Another insurer reported a 16-fold increase in less than a two-year period.

(f) Compounded drugs are not evaluated for safety or efficacy by the federal Food and Drug Administration (FDA). According to the FDA, compounded drugs carry significant health risks that can lead to permanent injury or death.

(g) In order to alleviate California's employers and insurers from this significant increase in costs, to enhance the efficiency of the workers' compensation system, and to ensure that injured workers receive safe, appropriate health care, the Legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, copacks, and medical foods and to create a new process for the prescription of compounded drugs, copacks, and medical foods.

SEC. 2. Section 139.3 of the Labor Code is amended to read:

139.3. (a) Notwithstanding any other law, to the extent those services are paid pursuant to Division 4 (commencing with Section 3200), it is unlawful for a physician to refer a person for clinical laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, outpatient surgery, diagnostic imaging goods or services, or pharmacy goods, whether for treatment or medical-legal purposes, if the physician or his or her immediate family has a financial interest with the person or in the entity that receives the referral.

(b) For purposes of this section and Section 139.31, the following shall apply:

(1) "Diagnostic imaging" includes, but is not limited to, all X-ray, computed axial tomography magnetic resonance imaging, nuclear medicine, positron emission tomography, mammography, and ultrasound goods and services.

(2) "Immediate family" includes the spouse and children of the physician, the parents of the physician, and the spouses of the children of the physician.

(3) "Physician" means a physician as defined in Section 3209.3.

(4) A "financial interest" includes, but is not limited to, any type of ownership, interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the physician refers a person for a good or service specified in subdivision (a). A financial interest also exists if there is an

indirect relationship between a physician and the referral recipient, including, but not limited to, an arrangement whereby a physician has an ownership interest in any entity that leases property to the referral recipient. Any financial interest transferred by a physician to, or otherwise established in, any person or entity for the purpose of avoiding the prohibition of this section shall be deemed a financial interest of the physician.

(5) A "physician's office" is either of the following:

(A) An office of a physician in solo practice.

(B) An office in which the services or goods are personally provided by the physician or by employees in that office, or personally by independent contractors in that office, in accordance with other provisions of law. Employees and independent contractors shall be licensed or certified when that licensure or certification is required by law.

(6) The "office of a group practice" is an office or offices in which two or more physicians are legally organized as a partnership, professional corporation, or not-for-profit corporation licensed according to subdivision (a) of Section 1204 of the Health and Safety Code for which all of the following are applicable:

(A) Each physician who is a member of the group provides substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(B) Substantially all of the services of the physicians who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group, and except that in the case of multispecialty clinics, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code, physician services are billed in the name of the multispecialty clinic and amounts so received are treated as receipts of the multispecialty clinic.

(C) The overhead expenses of, and the income from, the practice are distributed in accordance with methods previously determined by members of the group.

(7) Outpatient surgery includes both of the following:

(A) Any procedure performed on an outpatient basis in the operating rooms, ambulatory surgery rooms, endoscopy units, cardiac catheterization laboratories, or other sections of a

freestanding ambulatory surgery clinic, whether or not licensed under paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

(B) The ambulatory surgery itself.

(8) "Pharmacy goods" means any dangerous drug or dangerous device as defined by Section 4022 of the Business and Professions Code, any medical food as defined by Section 109971 of the Health and Safety Code, and any over-the-counter drug as classified by the federal Food and Drug Administration, *except over-the-counter drugs sold at commercially reasonable rates in physical retail outlets commonly accessed by the public*.

(c) (1) It is unlawful for a licensee to enter into an arrangement or scheme, such as a cross-referral arrangement, that the licensee knows, or should know, has a principal purpose of ensuring referrals by the licensee to a particular entity that, if the licensee directly made referrals to that entity, would be in violation of this section.

(2) It shall be unlawful for a physician to offer, deliver, receive, or accept any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for a referred evaluation or consultation.

(d) No claim for payment shall be presented by an entity to any individual, third-party payor, or other entity for any goods or services furnished pursuant to a referral prohibited under this section.

(e) A physician who refers to or seeks consultation from an organization in which the physician has a financial interest shall disclose this interest to the patient or if the patient is a minor, to the patient's parents or legal guardian in writing at the time of the referral.

(f) No insurer, self-insurer, or other payor shall pay a charge or lien for any goods or services resulting from a referral in violation of this section.

(g) A violation of subdivision (a) shall be a misdemeanor. The appropriate licensing board shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate disciplinary action if the licensee has committed unprofessional conduct. Violations of this section may also be subject to civil penalties of up to five thousand dollars ($5,000) for each offense,

which may be enforced by the Insurance Commissioner, Attorney General, or a district attorney. A violation of subdivision (c), (d), (e), or (f) is a public offense and is punishable upon conviction by a fine not exceeding fifteen thousand dollars ($15,000) for each violation and appropriate disciplinary action, including revocation of professional licensure, by the Medical Board of California or other appropriate governmental agency.

SEC. 3. Section 5307.1 of the Labor Code is amended to read:

5307.1. (a) The administrative director, after public hearings, shall adopt and revise periodically an official medical fee schedule that shall establish reasonable maximum fees paid for medical services other than physician services, drugs and pharmacy services, health care facility fees, home health care, and all other treatment, care, services, and goods described in Section 4600 and provided pursuant to this section. Except for physician services, all fees shall be in accordance with the fee-related structure and rules of the relevant Medicare and Medi-Cal payment systems, provided that employer liability for medical treatment, including issues of reasonableness, necessity, frequency, and duration, shall be determined in accordance with Section 4600. Commencing January 1, 2004, and continuing until the time the administrative director has adopted an official medical fee schedule in accordance with the fee-related structure and rules of the relevant Medicare payment systems, except for the components listed in subdivision (j), maximum reasonable fees shall be 120 percent of the estimated aggregate fees prescribed in the relevant Medicare payment system for the same class of services before application of the inflation factors provided in subdivision (g), except that for pharmacy services and drugs that are not otherwise covered by a Medicare fee schedule payment for facility services, the maximum reasonable fees shall be 100 percent of fees prescribed in the relevant Medi-Cal payment system. Upon adoption by the administrative director of an official medical fee schedule pursuant to this section, the maximum reasonable fees paid shall not exceed 120 percent of estimated aggregate fees prescribed in the Medicare payment system for the same class of services before application of the inflation factors provided in subdivision (g). Pharmacy services and drugs shall be subject to the requirements of this section, whether furnished through a pharmacy or dispensed directly by

the practitioner pursuant to subdivision (b) of Section 4024 of the Business and Professions Code.

(b) In order to comply with the standards specified in subdivision (f), the administrative director may adopt different conversion factors, diagnostic-related group weights, and other factors affecting payment amounts from those used in the Medicare payment system, provided estimated aggregate fees do not exceed 120 percent of the estimated aggregate fees paid for the same class of services in the relevant Medicare payment system.

(c) Notwithstanding subdivisions (a) and (d), the maximum facility fee for services performed in an ambulatory surgical center, or in a hospital outpatient department, shall not exceed 120 percent of the fee paid by Medicare for the same services performed in a hospital outpatient department.

(d) If the administrative director determines that a medical treatment, facility use, product, or service is not covered by a Medicare payment system, the administrative director shall establish maximum fees for that item, provided that the maximum fee paid shall not exceed 120 percent of the fees paid by Medicare for services that require comparable resources. If the administrative director determines that a pharmacy service or drug is not covered by a Medi-Cal payment system, the administrative director shall establish maximum fees for that item. However, the maximum fee paid shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources.

(e) (1) Prior to the adoption by the administrative director of a medical fee schedule pursuant to this section, for any treatment, facility use, product, or service not covered by a Medicare payment system, including acupuncture services, the maximum reasonable fee paid shall not exceed the fee specified in the official medical fee schedule in effect on December 31, 2003. For a pharmacy service, drug, or other pharmacy product that is not covered by a Medi-Cal payment system, the maximum fee shall be 83 percent of the average wholesale price of the lowest priced product of equivalent therapeutic effect.

(2) (A) Until the date that the administrative director adopts an official medical fee schedule for compounded drug products, the maximum reasonable fee for a compounded drug product shall be the sum of the compounding fee for route of administration and quantity, the dosage compounding fee, the sterility fee, if

applicable, and the dispensing fee, all as provided by the Medi-Cal payment system, plus the sum of the amounts allowed for the ingredients of the compounded drug product pursuant to this paragraph.

(B) If an ingredient is available in bulk form from three or more suppliers listed in the current version of a national pricing compendium for the same chemical ingredient and dosage form, the unit price shall be the lesser of 150 percent of the unit price of the lowest cost alternative for purchases made in quantities of the largest packaging size available from each supplier or the unit price listed in the Medi-Cal database.

(C) If an ingredient not subject to subparagraph (B) is listed in the Medi-Cal database, the unit price shall be the lesser of the price listed in the Medi-Cal database or 120 percent of the documented paid cost incurred by the pharmacy that compounds the drug product.

(D) If an ingredient not subject to subparagraph (B) is not listed in the Medi-Cal database, the unit price shall be the lesser of 83 percent of the average wholesale price for the manufacturer as published in the current version of a national compendium of drug pricing or the documented paid cost incurred by the pharmacy that compounds the drug product. Both the average wholesale price for the manufacturer and the documented paid cost shall be determined with respect to the actual source of the ingredients used in the compounded drug product.

(E) A fee shall not be allowed for any ingredient that is not identified by a valid National Drug Code, number of units, unit price, and where applicable, the documented paid cost per unit. A fee shall not be allowed for a compounded drug ingredient if complete information for any component of the fee according to this subdivision, or as may be required by regulations adopted by the administrative director, is not included in the initial billing to the claims administrator.

(3) (A) The fee for any product dispensed by a physician shall not exceed the lesser of 120 percent of the physician's documented paid cost or the physician's documented paid cost plus two hundred fifty dollars ($250).

(B) For a compounded drug product dispensed by a physician, the fee shall not exceed the lesser of the amount allowed pursuant to subparagraph (A) or the amount allowed for the compounded

drug product pursuant to paragraph (2). For a pharmacy-compounded product, the amount allowed pursuant to paragraph (2) shall be determined without regard to the compounding pharmacist's documented paid cost. A billing for a compounded drug product dispensed by a physician shall include the pricing information in accordance with subparagraph (E) of paragraph (2).

(C) This paragraph shall apply until the date that the administrative director adopts an official medical fee schedule specifically applicable to physician-dispensed products.

(4) For the purposes of this subdivision, the following definitions apply:

(A) "Average wholesale price" means the price published as the average wholesale price according to a national compendium of drug pricing.

(B) "Compounded drug product" means any drug product subject to Article 4.5 (commencing with Section 1735) of Division 17 of Title 16 of the California Code of Regulations or other regulation adopted by the State Board of Pharmacy to govern the practice of compounding.

(C) "Dispensed" does not mean a product administered or applied to a patient in the prescriber's office.

(D) "Documented paid cost" means the unit price paid for the specific product or for each component used in the product as documented by invoices, proof of payment, and inventory records as applicable, or as documented in accordance with regulations that may be adopted by the administrative director, net of rebates, discounts, and any other immediate or anticipated cost adjustments.

(E) "Product" means any object or substance that is reimbursable separately from the physician's fee for services, including, but not limited to, a drug, device, or medical food.

(f) Within the limits provided by this section, the rates or fees established shall be adequate to ensure a reasonable standard of services and care for injured employees.

(g) (1) (A) Notwithstanding any other law, the official medical fee schedule shall be adjusted to conform to any relevant changes in the Medicare and Medi-Cal payment systems no later than 60 days after the effective date of those changes, provided that both of the following conditions are met:

(i) The annual inflation adjustment for facility fees for inpatient hospital services provided by acute care hospitals and for hospital outpatient services shall be determined solely by the estimated increase in the hospital market basket for the 12 months beginning October 1 of the preceding calendar year.

(ii) The annual update in the operating standardized amount and capital standard rate for inpatient hospital services provided by hospitals excluded from the Medicare prospective payment system for acute care hospitals and the conversion factor for hospital outpatient services shall be determined solely by the estimated increase in the hospital market basket for excluded hospitals for the 12 months beginning October 1 of the preceding calendar year.

(B) The update factors contained in clauses (i) and (ii) of subparagraph (A) shall be applied beginning with the first update in the Medicare fee schedule payment amounts after December 31, 2003.

(2) The administrative director shall determine the effective date of the changes, and shall issue an order, exempt from Sections 5307.3 and 5307.4 and the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), informing the public of the changes and their effective date. All orders issued pursuant to this paragraph shall be published on the Internet Web site of the Division of Workers' Compensation.

(3) For the purposes of this subdivision, the following definitions apply:

(A) "Medicare Economic Index" means the input price index used by the federal Centers for Medicare and Medicaid Services to measure changes in the costs of a providing physician and other services paid under the resource-based relative value scale.

(B) "Hospital market basket" means the input price index used by the federal Centers for Medicare and Medicaid Services to measure changes in the costs of providing inpatient hospital services provided by acute care hospitals that are included in the Medicare prospective payment system.

(C) "Hospital market basket for excluded hospitals" means the input price index used by the federal Centers for Medicare and Medicaid Services to measure changes in the costs of providing inpatient services by hospitals that are excluded from the Medicare prospective payment system.

(h) This section does not prohibit an employer or insurer from contracting with a medical provider for reimbursement rates different from those prescribed in the official medical fee schedule.

(i) Except as provided in Section 4626, the official medical fee schedule shall not apply to medical-legal expenses, as that term is defined by Section 4620.

(j) The following Medicare payment system components shall not become part of the official medical fee schedule until January 1, 2005:

(1) Inpatient skilled nursing facility care.

(2) Home health agency services.

(3) Inpatient services furnished by hospitals that are exempt from the prospective payment system for general acute care hospitals.

(4) Outpatient renal dialysis services.

(k) Notwithstanding subdivision (a), for the calendar years 2004 and 2005, the existing official medical fee schedule rates for physician services shall remain in effect, but these rates shall be reduced by 5 percent. The administrative director may reduce fees of individual procedures by different amounts, but shall not reduce the fee for a procedure that is currently reimbursed at a rate at or below the Medicare rate for the same procedure.

(*l*) Notwithstanding subdivision (a), the administrative director, commencing January 1, 2006, shall have the authority, after public hearings, to adopt and revise, no less frequently than biennially, an official medical fee schedule for physician services. If the administrative director fails to adopt an official medical fee schedule for physician services by January 1, 2006, the existing official medical fee schedule rates for physician services shall remain in effect until a new schedule is adopted or the existing schedule is revised.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

the meaning of Section 6 of Article XIII B of the California Constitution.

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